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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,128	02/04/2002	Joel Krasnow	3414/1	6002

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EXAMINER	
BAHAR, MOJDEH	
ART UNIT	**PAPER NUMBER**
1617	5

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,128	Applicant(s) KRASNOW, JOEL	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *7-21, 23-24, 26-33, 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 22, 25 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Information Disclosure Statement of July 1, 2002 has not been considered, since the references were not found in the office.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-34, drawn to a therapeutic combination comprising a COX-2 inhibitor compound source and a steroid compound, classified in class 514, subclass 406, 473, 171, 177, 178, for example.

II. Claims 35-55, drawn to a method of treating dysmenorrhea in a patient employing a therapeutic combination comprising a COX-2 inhibitor compound source and a steroid compound, classified in class 514, subclass 406, 473, 171, 177, 178, for example.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case dysmenorrhea can be treated by an estrogen or a cox-2 inhibitor alone.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Specie Election

Claims 1-24, 26, 34-46 and 48 are generic to a plurality of disclosed patentably distinct species of steroid compounds. Claims 1-24, 26, 34-46 and 48 as presented contain such a vast multitude of possibilities and permutations of steroid compounds classified in class 514, subclasses 171, 177 and 178 for example, that the search for each and every species encompassed in the claims presents an undue burden on the office. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided for in MPEP 803.02. These species are considered to be distinct inventions since the species are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents.

Claims 1-5, 10, 12, 14, 16-17, 19, 21-36, 44, 46-55 are generic to a plurality of disclosed patentably distinct species of COX-2 inhibitors. Claims 1-5, 10, 12, 14, 16-17, 19, 21-36, 44 and 46 as presented contain such a vast multitude of possibilities and permutations of COX-2 inhibitors classified in class 514, subclasses 406, 473, for example, that the search for each and every species encompassed in the claims presents an undue burden on the office. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided for in MPEP 803.02. These species are considered to be distinct inventions since the species are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, **one specific steroid compound and one specific COX-2 inhibitor,** even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Mr. Warner on September 10, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-34 and the species celecoxib and ethinyl estradiol. Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 7-21, 23-24 and 26-33 are withdrawn, as drawn to non-elected species. Claims 1-6, 22 25 and 34 are herein examined on the merits in so far as they read on the elected species of celecoxib and ethinyl estradiol.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Deligeorglou.

Deligeorglou teaches the employment of a pharmaceutical composition comprising oral contraceptives in a method of treating dysmenorrhea. Deligeorglou further discloses that if good relief of dysmenorrhea is not achieved with oral contraceptives alone, a prostaglandin inhibitor can be added. Deligeorglou specifically teaches the employment of cyclooxygenase inhibitors in treating dysmenorrhea, see particularly *Management* on page 241.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 22, 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deligeorglou (*Dysmenorrhea*. Ann. N Y Acad. Sci. 2000; 900:237-44) in view of PDR (50th Ed., 1996) and Harrison et al. (USPN 6,086,909).

Deligeorglou teaches the employment of a pharmaceutical composition comprising oral contraceptives in a method of treating dysmenorrhea. Deligeorglou further discloses that if good relief of dysmenorrhea is not achieved with oral contraceptives alone, a prostaglandin inhibitor can be added. Deligeorglou specifically teaches the employment of cyclooxygenase inhibitors in treating dysmenorrhea, see particularly *Management* on page 241.

Deligeorglou does not particularly teach the employment of ethinyl estradiol and celecoxib in its method of treating dysmenorrhea. Neither does it teach the incorporation of ethinyl estradiol and celecoxib in a single composition.

PDR (50th Ed., 1996) teaches that the administration of a pharmaceutical composition comprising ethinyl estradiol diminishes pain during menstruation and reduces the incidence of dysmenorrhea, see in particular pages 2090 and 2093.

Harrison et al. (USPN 6,086,909) teaches a pharmaceutical composition comprising non-estroidal anti-inflammatory drugs such as celecoxib suitable for employment in a method of treating dysmenorrhea, see in particular col.2, lines 18-36 and abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ ethinyl estradiol and celecoxib in a combination composition.

One of ordinary skill in the art would have been motivated to employ ethinyl estradiol and celecoxib in a combination composition because the prior art teaches the employment of both classes of pharmaceuticals, i.e., oral contraceptives and COX inhibitors, in a method of

treating dysmenorrhea. Furthermore, each of the actives is individually known to be useful in a method of treating dysmenorrhea. Combining two agents which are known to be useful to treat dysmenorrhea individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
October 15, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER
10/21/02